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Rostoker et al.

[11] **3,906,550**

[45] **Sept. 23, 1975**

[54] **PROSTHETIC DEVICE HAVING A POROUS FIBER METAL STRUCTURE**

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[52] U.S. Cl. ..... **3/1.912**; 3/1.913; 3/1.9; 128/92 C; 128/92 BC; 32/10 A; 29/419

[51] Int. Cl.² A61F 1/24; A61C 13/30

[58] Field of Search ..... 3/1, 1.9–1.913; 128/92 C, 92 CA, 92 BC, 92 R; 32/10 A

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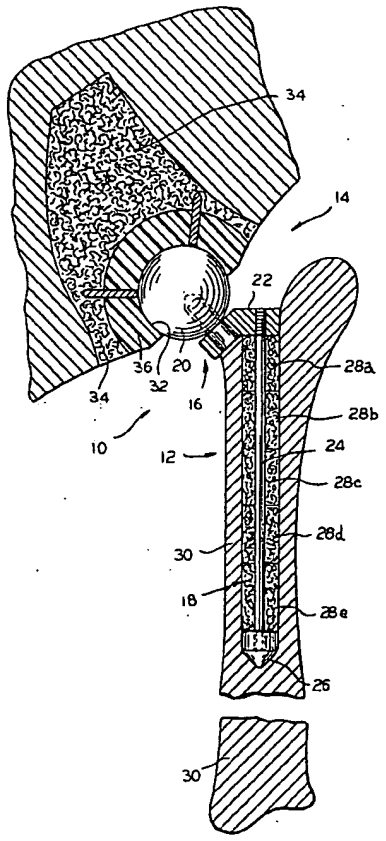
[57] **ABSTRACT**

Prosthetic devices for replacement, attachment and reconstruction of bone structure in the skeletal systems of humans and animals. The prosthetic devices may be a fiber metal structure of sufficient section to support loads adequately or may include a solid load carrying member having a fiber metal structure secured to the surface thereof. The fiber metal structure is sintered and open-pored so that the bone and tissue into which the prosthetic device is implanted will grow into such fiber metal structure.

To provide the proper interlock between fibers, the individual fiber strands are prekinked prior to cutting into the desired length. The kink pattern should be substantially sinusoidal. Preferably such kink pattern should have an amplitude (H) to period (W) relationship, H/W of 0.24 or greater.

10 Claims, 6 Drawing Figures



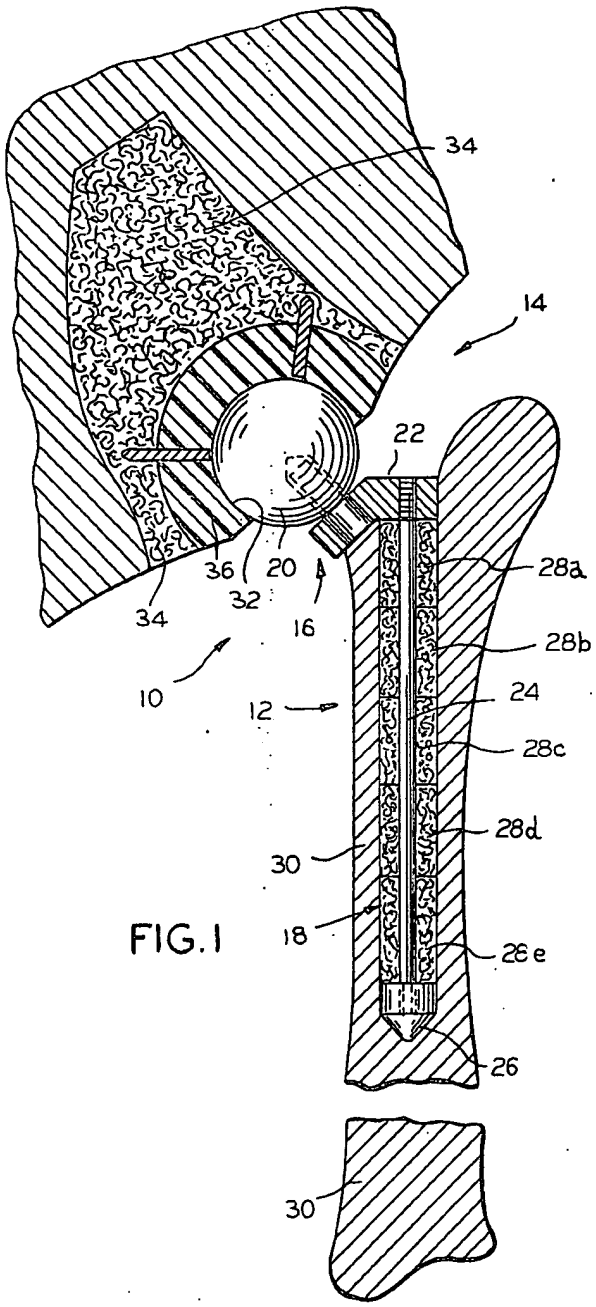


FIG. 1

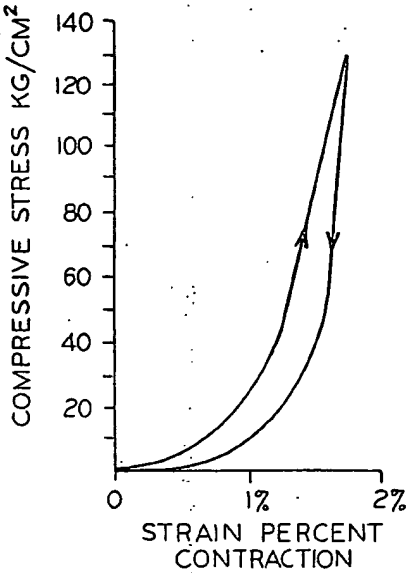


FIG. 2

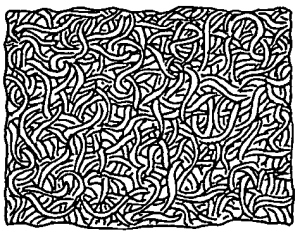


FIG. 4

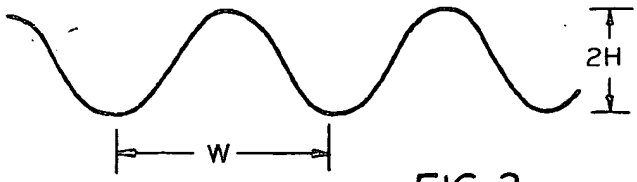


FIG. 3

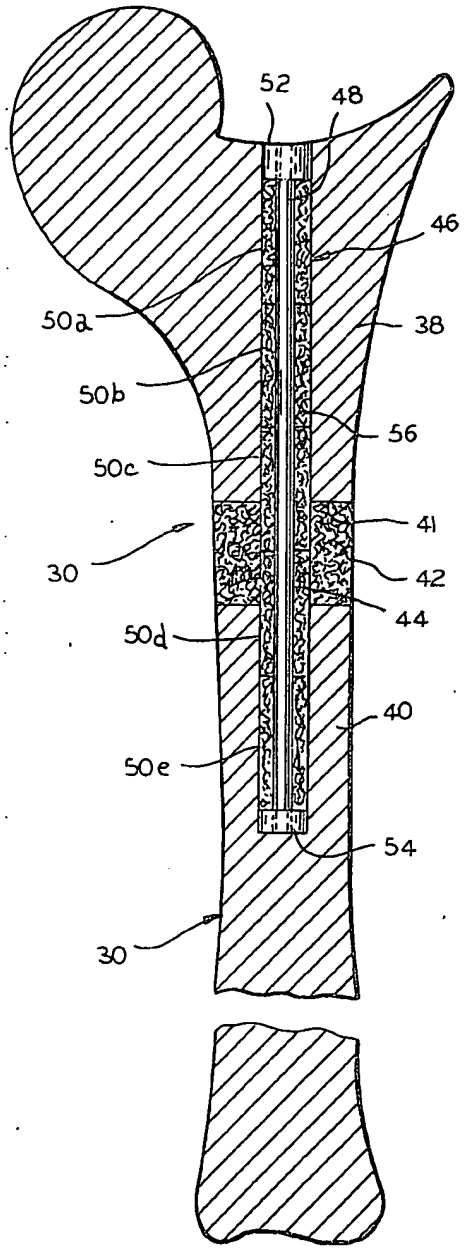

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FIG.5

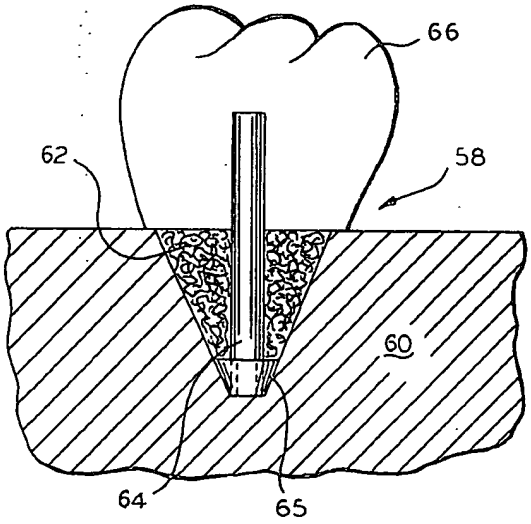
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FIG.6

PROSTHETIC DEVICE HAVING A POROUS FIBER METAL STRUCTURE

BACKGROUND OF THE INVENTION

This invention relates to prosthetic devices for replacement, reconstruction and attachment in the skeletal system of humans and animals; and more particularly is directed to a prosthetic device including a porous fiber metal structure.

Prosthetic devices are used to partially or completely replace joints or bone segments in the skeletal structure of humans or animals. One of the major problems involved in the use of prosthetic devices is the attachment of the prosthetic implant to the adjacent bone. There are four principal methods by which the device can be attached to the bone. These methods include: (1). Impaction of the prosthetic stem into the medullary cavity of the bone; (2). Mechanical internal fixation, e.g., screws; (3). Methyl methacrylate polymerizing "in situ" used as a cement or filler between the prosthesis and the bone; and (4). Porous materials into which the bone can grow. Each of these methods presents problems that can cause failure of the prosthetic implant.

The devices which are impacted into the medullary cavity are held in place by a compressive residual stress interaction which may be more commonly referred to as a force fit. If this stress interaction is relaxed in the surrounding bone, due to physical or biological processes, the attachment is lost and the device becomes loose, thereby requiring surgical removal and refitting of the prosthesis.

Mechanical internal fixation produces acceptable limited term attachments. However, in long term use the device may become loose and thereby require replacement.

Polymethyl methacrylate has also produced acceptable limited term attachments. However, doubts still exist as to the overall safety of its use from a biological point of view partly from damage to surrounding tissue from monomer and heat interaction, and partly that the plastics may age in the body fluid thereby becoming brittle and tending to crack or crumble.

An open-pore material into which bone could grow should provide ideal skeletal fixation. Numerous materials and processes for producing porous aggregates have been disclosed which serve this purpose. For example, see U.S. Pat. No. 3,314,420. Typically these aggregates are powder metals or powder ceramics which are compressed and sintered to produce a porous but relatively strong body. In order to obtain the high level of porosity and acceptable green strength, rather fine powders are required, the use of which substantially limits the size of the pores. During sintering much of the porosity ceases to become interconnecting and thus a high proportion of the pores at the surface become isolated from the interior of the body. This isolation limits bone ingrowth and results in a situation similar to the roughened surface of a solid. Furthermore, the mechanical properties of sintered powders are not ideal; for example, porous consolidated ceramics are very weak and brittle, and cracks propagate quickly throughout the whole body of the porous aggregate at low stresses or with small impact energies. Consolidated metal powders with porosities in the range of 40–60% void, are stronger than the consolidated ceramics but still are very brittle and have poor toughness. Moreover, sintered metal powders are susceptible to fatigue failure. Both sintered ceramics and metal powders have compliances which more closely approximate the pore free material. Compliance is defined as the change in elastic strain per unit change in stress.

The subject invention provides a prosthetic device which is non-toxic, compatible and not subject to loosening or movement after implantation, and further includes the provision of an open-pore attachment for bone ingrowth which attachment is highly compliant, not brittle, resistant to crack propagation and has a broad range of readily controllable pore sizes.

SUMMARY OF THE INVENTION

There is provided by this invention a prosthetic device including a porous aggregate produced by molding and sintering short metal fibers. The sintering process creates metallurgical bonds at the points of contact of the fibers. Thus, the fiber metal aggregate has considerable mechanical strength due to mechanical interlock of the fibers and the sintered bonds.

The degree of mechanical interlock and mechanical strength of the porous aggregate is appreciably improved if the wire is kinked prior to being cut into the short metal fibers. The kinking pattern should be sinusoidal. Preferably, the ratio of amplitude and period of the sine wave should be 0.24 or greater. After the kinking is formed, the wire is cut into the desired lengths.

By using fiber metals the range of pore sizes can be readily controlled and the attachment is not subject to the crack propagation and low strength problems associated with ceramics or powdered metal attachments and provides a highly compliant, non-brittle connection. Moreover, in view of the use of fiber metals, the pores are interconnecting and remain so after sintering. Thus bone growth can penetrate for a substantial distance into the fiber metal structure and thereby provide a very secure connection. By the appropriate selection of the fiber metal composition, an essentially inert attachment can be achieved; hence, the fiber metal attachment is not subject to the aging problems or reaction problems of the plastics of the prior art. Since the pore size can be readily controlled by the pressing and forming parameters, the density of the sintered composite can approximate the density of the bone to which the prosthetic device is implanted.

BRIEF DESCRIPTION OF THE DRAWINGS

Referring to the drawings in which the same characters of reference are employed to indicate corresponding similar parts throughout the several figures of the drawings:

FIG. 1 is a vertical sectional view illustrating an exemplary hip joint prosthesis;

FIG. 2 is a stress-strain diagram for a molded and sintered Co-Cr-W alloy fiber aggregate;

FIG. 3 illustrates a sinusoidal kinking pattern of a wire length prior to being cut into the fiber strands used in the fiber metal structure of FIG. 1;

FIG. 4 illustrates an enlargement of a portion of a molded fiber metal structure;

FIG. 5 is a vertical sectional view depicting a femur having a bone segment reconstruction prosthesis; and

FIG. 6 is a vertical view of a mounting for a dental prosthesis.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to FIG. 1 of the drawings, the reference numeral 10 indicates generally a hip joint prosthesis which is exemplary of the prosthetic devices embodying the principles of the subject invention. The joint prosthesis 10 comprises two individual prosthesis, a femur prosthesis 12 and a acetabulum prosthesis 14. The femur prosthesis 12 comprises a load carrying means 16 of solid construction and a sintered fiber metal attachment structure indicated generally by the reference numeral 18.

The solid load carrying means 16 includes a ball 20 carried on a flange 22, which in turn is mounted to a rod 24 having a cup-shaped bottom end member 26. The fiber metal attachment structure 18 includes a plurality of tubular fiber metal segments 28*a*, 28*b*, 28*c*, 28*d*, and 28*e*.

The rod 24 and segments 28*a* through 28*e* are inserted into the medullary cavity of the femur 30 which is appropriately reamed and is thus fixed in place so that the ball 20 is properly orientated with respect to the hip socket 32. As the healing process takes place, the bone which is adjacent the fiber metal segments 28*a* through 28*e* grows into the attachment 18. It has been observed that after the bone ingrowth has proceeded to a substantial degree, a secure fixation is produced between the ingrown bone and the fiber metal implant.

The attachment segments 28*a* through 28*e* can be secured to the rod 24 in a number of ways. The most effective way is to metallurgically bond the fibers contacting the surface of the rod thereto; however, it will be appreciated that the flange 22 and end member 26 when tightened also act to hold the attachment segments 28 in place. Other methods by which the segments 28 are mounted to the rod 24, include cementing or the like or mechnical fixation; however, as indicated above metallurgical attachment is preferred.

The solid load carrying rod 24 or a similar member is normally used when tension and bending loads may be anticipated. However, where only compressive loads are experienced, the fiber metal structure 18 may be used without such rod 24. However, in some situations where stresses and strains are realized, a fiber metal structure of substantial area may be used without the rod 24.

The acetabulum prosthesis 14 includes fiber metal attachment component 34 and a solid wear insert 36. The fiber metal attachment is molded into the proper shape and then fitted into a cavity formed in the acetabulum during surgery. Bone ingrowth will hold the fiber component 34 rigidly in place. Since a fiber metal surface is probably not particularly wear resistant, the wear insert 36 is molded integral with the fiber component 34. Furthermore, the insert 36 not subject to bone ingrowth can be held in place mechanically so that it can be subsequently removed and replaced if necessary.

In another prosthetic system, a union may be accomplished between the upper and lower portions 38 and 40 of a severed femur 30 generally as shown in FIG. 5. As is seen, the severance space 41 is filled with a cylindrical sintered fiber metal member 42 having a center core hole 44 through which a sintered fiber-sleeved shaft 46 is passed, to provide fixation to the extremities of the femur 30. The shaft 46 includes a solid center member 48, sintered fiber metal sleeves 50*a*, 50*b*, 50*c*, 50*d* and 50*e*, and end members 52 and 54. Shaft 46 is fitted into the medullary cavity 56 of the femur 30 which is appropriately reamed.

In still another prosthetic application, a device 58, as shown in FIG. 6, may be implanted in the jawbones 60 of humans or animals as a basis for mounting artificial teeth or dentures. The dental prosthesis 58 comprises a monolithic sintered fiber metal member 62, and a solid center shaft 64 passing centrally through the fiber member 62. Shaft 64 includes a flanged bottom 65. When bone or tissue grows into the fiber member 62, the upper end of the shaft 40 is securely held in place and an artificial tooth 66 can then be mounted thereon. The ingrowth of gingival tissue provides a bacterial seal.

The fiber metal segments 28, and the fiber metal attachment component 34 shown in FIG. 1, and the fiber metal member 42 and sleeves 50 shown in FIG. 5, and the fiber metal member 62 shown in FIG. 6 are all porous aggregates produced by molding and sintering short metal fibers. The points of contact between fibers become metallurgical bonded during sintering. Thus, the fiber metal aggregate has considerable mechanical strength due to the sintered bonds and the mechanical interlocks.

Short lengths of fine wire such as stainless steel, unalloyed titanium or Co-Cr-W alloy, are mechanically molded into the desired precise shapes using constraining dies and moving punches. When loading the wire charge of short metal fibers in the die during molding, the long axes thereof, should be on the most part coaxial with the punch motion. Upon applying the proper pressure with the dies and punches, a three-dimensional mechanically interlocked network of fibers is formed.

The degree of interlock and unsintered or "green" strength of a pressing with the dies, is substantially increased if the original wire is prekinked prior to cutting the wire into the short fibers. The desired kinking can be accomplished by passing the wire through a set of meshing gears.

It has been found that the wire should be prekinked into a sinusoidal pattern to provide the greatest mechanical interlock, as shown in FIG. 3. Thereafter, the kinked sinusoidal wire is cut into the desired short fiber lengths.

To provide the optimum interlock the kink pattern should have an amplitude (H) to period relationship (W), H/W of 0.24 or greater.

The kinked short fiber strands of 316 L stainless steel; unalloyed titanium and Co-Cr-W alloy wire, are molded into the precise shape for the fiber metal aggregate as aforestated, using constraining dies and moving punches. The choice of the wire size and the density of the fiber strands loaded in the dies will govern the final parameter dimensions of the fiber metal aggregate.

The molding operation is followed by a sintering stage in which points of contact become actual metallurgical bonds. Adequate bonding has been obtained with oven temperatures within the range of 1070° – 1240° C for approximately 2 hours.

Repressing, using the same die and punch tooling, of the sintered metal fiber aggregate must be done to enable the aggregate to be formed into precise and reproducible dimensions which are necessary for good clinical responses.

The sintered fiber metal aggregates shown in FIGS. 1, 5 and 6 may be molded having void or a porosity of 40 to 50 percent per unit area. A porosity of 60% could also be achieved, but the green strength is generally too fragile, and therefore, could effect the dimensional control because of elastic recovery. Also fiber metal aggregate having such greater porosities are not sufficiently firm at the edges and tend to crumble.

Wire sizes as fine as 0.013 centimeters in diameter and as coarse as 0.030 centimeters in diameter have been satisfactorily molded. In the molded and sintered fiber metal aggregate, the metal fibers are completely interconnected. The pore shapes as may be seen from FIG. 4, which is a magnification of a portion of a sintered-molded fiber metal aggregate, cannot be described in any simple geometric shape. The largest principal dimension of the pores is approximately equal to the wire diameter when the void content is about 50 percent. However, pressing or molding to higher densities would lead to more constricted pore sizes.

Wire is cut to lengths ranging from 1.3 to 3.8 centimeters. The longer the wire, the more difficult it is to feed into dies. On the other hand, long wire lengths give more interlock and better molded strengths.

Turning now to FIG. 2, a graphical representation of a reversible (elastic) stress strain cycle is shown for Co-Cr-W alloy wire of 0.023 centimeters in diameter, molded to 50 percent porosity and sintered at 1240° C for 3 hours. Before testing and obtaining the data for FIG. 2, the sintered specimen was recompressed to a 7% reduction in height.

The elastic properties of Co-Cr-W alloy and other metal of the same class, such as stainless steel and titanium have elastic properties more like an elastomer than a metal. A sintered specimen shows a purely plastic strain range of about 3–10 percent on the application of very small loads. Thereafter, there is an elastic strain range of about 3 percent in which the modulus is a continuous function of strain (FIG. 2). For the strain range of about 1 percent, the modulus is about 10^4kg/cm2 for the sintered fiber metal structure.

The sintered porous fiber metal structure disclosed herein has an elastic modulus substantially less than the elastic modulus for porous metals produced by sintered powders. This enables the sintered porous fiber metal structure to be an effective interface between bone tissue and a load-bearing prosthesis; and it further provides a very high compliance (large strains per unit applied stress), which is a safeguard against high localized stresses at the prothesis-tissue interface.

By repressing procedures the external dimensions of prostheses may be precisely regulated to the excavation so that a zero clearance fit exists. The zero clearance fit is vital to the clinical success of fixation by bone and soft tissue. In the absence of a zero clearance fit, the prothesis is isolated by fibrous or non-functional tissue. For a tooth root prosthesis this leads to loosening. Other porous materials cannot easily be sized to precise dimensions.

The foregoing specification and description are intended as illustrative of the invention, the scope of which is defined in the following claims.

We claim:

1. A prosthetic device for incorporation into the skeletal structure of a human or animal including:

a porous fiber metal structure formed from a plurality of substantially, sinusoidally shaped fiber strands, each of said fibers having a ratio of amplitude to period of substantially 0.24 or greater, said strands being metallurgically bonded to each other at their points of contact, said fiber metal structure providing at least a portion of the surface of said prosthetic device adjacent said skeletal structure to enable bone and soft tissue growth into said metal structure, said period being substantially the length of a cycle of said sinusoidal fiber strand and said amplitude being substantially the height/2 between a positive peak and a negative peak of said sinusoidal fiber strand.

2. The prosthetic device of claim 1, wherein said fiber metal structure is between 10% and 70% porous.

3. The prosthetic device of claim 1, wherein the diameter of said fiber strands is between about 0.013 centimeters and 0.030 centimeters.

4. The prosthetic device of claim 1, wherein the length of said fiber strands is between about 1.3 centimeter and 3.8 centimeters.

5. The prosthetic device of claim 1 includes a non-compressible rod, said fiber metal structure being secured to the outside of said rod.

6. The prosthetic device of claim 1, wherein said fiber metal structure is selected from the group consisting of titanium, Co-Cr-W alloy, stainless steel, tantalum and zirconium.

7. The prosthetic device of claim 1, includes:

a wear resistant member, said fiber metal structure being mounted on said wear member, said fiber metal structure adapted to be in contact with said skeletal structure when implanted therein.

8. The prosthetic device of claim 5, wherein said fiber metal structure comprises a plurality of cylindrical segments mounted on and surrounding said rod.

9. The prosthetic device of claim 8 further includes:

a second porous fiber metal structure having a bore therein, said bore being dimensioned to receive said rod with said segments thereon.

10. The prosthetic device of claim 1 wherein said device is a dental prosthesis, including an upstanding mounting member mounted in said fiber metal structure and extending outward therefrom, said fiber metal structure extending around said upstanding member for operatively contacting the jaw bone to receive the growth of said jaw bone and gingival soft tissue.

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